IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:

First Named Inventor: RAYMOND J. BERGERON

Art Unit: 1614

Appln. No.: 10/091,591

Examiner: Anderson, James

Filed: March 7, 2002

Confirmation No.: 9684

For: METHOD AND COMPOSITION FOR THE TREATMENT OF DIARRHEA AND GASTROINTESTINAL SPASMS

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REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Reply is responsive to the Examiner's Answer dated June 11, 2009.

Status of claims is on page 2 of this paper.

Grounds of rejection to be reviewed is on page 2 of this paper.

Argument begins on page 2 of this paper.

Request for Oral hearing is enclosed herein.

STATUS OF CLAIMS

The above-captioned application was filed with original claims 1-6. This is an appeal from the final rejection of claims 1-6.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-6 comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

Whether claims 1-6 comply with the written description requirement of 35 U.S.C. § 112, first paragraph as containing new matter.

Whether claims 1-6 are patentable under 35 U.S.C. § 103(a) over Frydman et al. (U.S. Patent No. 5,889,061).

ARGUMENT

Reconsideration and withdrawal of the rejections in view of the remarks presented herein is respectfully requested.

35 U.S.C. § 112, first paragraph

With respect to the Written Description rejection, the Examiner has condensed the grounds for the rejection to whether or not appellant had sufficient possession of that part of the invention that appellant attempted to remove from the ambit of the claims by a negative proviso.

Thus, the original claims were sufficiently broad to include certain *trans* isomers. Appellant amended the claims to exclude, via a negative proviso, two species of said *trans* isomers. The Examiner acknowledged that the present specification specifically described one of the *trans* species, but failed to describe the other. The Examiner then concluded that the disclosure of only a single species of *trans* isomer was insufficient to

establish sufficient possession of the *trans* isomer aspect of the invention under 35 USC 112 to support the proposed negative proviso.

The Examiner did not, however, cite to any authority as to the number of species necessary to establish possession of a subgenus of the invention. The sole basis for the stated conclusion is the Examiner's unsupported opinion.

As evidence of the incongruity of the Examiner's position, consider that the original claims, which covered all *trans* isomers, were considered by the Examiner to be sufficiently supported to satisfy the Written Description requirement of 35 USC 112. Thus, these claims were never subjected to a "Written Description" rejection on the basis that 35 USC 112 support for this subgenus of isomers did not exist in the specification. It therefore must follow that the Examiner considered the claims to comply with the "written description" requirements of 35 USC 112 with respect to all included *trans* isomers. Accordingly, if the prior broader claims are supported with respect to all *trans* isomers embraced by the claims, it is inconsistent to argue that claims that are now narrower as to included *trans* isomers are not supported.

In any event, it is appellant's position that the Examiner has misinterpreted the law with respect to negative provisos.

Several US cases have suggested that, historically, the law favored allowing applicants to insert undisclosed disclaimers into patent claims. In 1977, the CCPA stated that the idea that one who fully discloses and teaches how to make and use a genus and species therein, has somehow failed to disclose that genus minus two of those species, was said to "result in an overly-legalistic application of the law" [*In re Johnson*, 194 USPQ 187, 196; 558 F.2d 1008, 1019 (CCPA 1977)]. In holding that to deny applicants the ability to narrow claims to a subgenus simply because there is no express support in the specification would be to "demand that patent applicants be all knowing and foretell

what prior art be cited so that they can layer their claim scope accordingly throughout the disclosure". Applicants would have to "either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted" [*In re Driscoll*, 195 USPQ 434, 438; 562 F.2d 1245, 1249 (1977)].

Despite these early cases holding that undisclosed disclaimers are permissible, the law later changed, making it more difficult to add an undisclosed disclaimer to pending claims in a US application. In finding that addition of a negative disclaimer to a pending claim introduced concepts not described in the application as originally filed, the court in 1984 established that any negative disclaimer or exclusionary proviso had to find support in the patent application as filed [*parte Grasselli*, 231 USPQ 395; 738 F.2d 453 (Fed. Cir. 1984)]. Indeed, this was the rule applied by patent examiners; i.e., where a negative disclaimer which does not have basis in the application as filed is generally impermissible.

However, two cases in 1996 softened this approach. In one case, a decision to permit addition of a disclaimer to the claims was permitted because the application as originally filed ***suggested*** that the applicant possessed the idea of the invention absent the disclaimed subject matter [*Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993)]. In the other case, the applicant was able to expressly limit the claims so that they included only a portion of the whole invention, on the grounds that a description of the whole invention in the application as filed also describes a portion of the whole invention [*Ex parte Shalati*, 1996 WL 1771413 (Bd. Pat. App. & Inter. 1996)]. These cases strongly suggest that an applicant in the US may use a negative disclaimer that is not expressly set forth in the application at the time of filing in situations where the application as filed conveys that selected portions of the invention may be excised.

In *Ex parte Macphail*, Appeal No. 2004-1557-Application 09/451,942, the Examiner's rejection was characterized by the Board as: "tantamount to a per se prohibition of any negative limitation that does not have expressly stated support in the originally filed specification", citing *Grasselli* and stating: "Grasselli [...]appears to provide support for the examiner's position because the Board found that the negative limitation added to the claims introduced new concepts in violation of the description requirement of the first paragraph of 35 U.S.C. § 112"

The Board, however, in *Macphail*, rejected this reasoning and essentially overturned Grasselli: "In the subsequent case of Ex parte Parks [...] the Board did not adhere to Grasselli's per se prohibition of negative limitations that lack express written description support in the originally filed disclosure, and, instead, resorted to a more reasonable test of what the originally filed disclosure would have conveyed to one having ordinary skill in the art"

In *Ex parte Smith*, Appeal 2007-2771-Application 10/418,661-Decided: September 24, 2007, the Board had to decide whether:

> 1. Has the Examiner demonstrated that the negative limitations, "the mat is non-perforated" and "deck does not contact the single ply membrane" recited in claims 3, and 5 through 22 and/or 26 introduce a new concept not provided in the application disclosure, as originally filed, in violation of the first paragraph of 35 U.S.C. § 112?
> 2. Has the Examiner demonstrated that the negative limitation "membrane is not adhered to the roof deck" recited in claims 23 through 25 and 27 introduces a new concept not provided in the application disclosure, as originally filed, in violation of the first paragraph of 35 U.S.C. § 112?

In overruling the Examiner the Board stated:

> *According to In re Wertheim,* 541 F.2d 257, 262-265, 191 USPQ 90, 96-98 (CCPA 1976): [...] The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material. [...]It is not necessary that the application describe the claim limitations exactly....but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. [*Citations omitted.*] [...] If lack of literal support alone were enough to support a rejection under 112, then the statement of *In re Lukach* [442 F.2d 967, 969, 169 USPQ 795, 796 (CCPA 1971)] that "the invention claimed does not have be described in *ipsis verbis* in order to satisfy the description requirement of [§]112," is empty verbiage.

See also *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560-64, 19 USPQ2d 1111, 1114-17 (Fed. Cir. 1991).

In sum, the Examiner bemoans the fact that the present specification discloses only the subgenus and one species, but does not either:

- 1] Indicate why such a disclosure does not demonstrate possession of the invention, or
- 2] Indicate just how many species must be disclosed in order to satisfy the Written Description section of 35 USC 112.

It is respectfully submitted for the reasons stated above and in accordance with the legal authority discussed therein, the negative proviso is appropriate within the meaning of 35 USC 112.

Accordingly, a reversal of this ground of rejection is respectfully requested.

35 U.S.C. § 112, First Paragraph as Containing New Matter

With respect to the rejection of the claims under 35 U.S.C. § 112, first paragraph, it is the Examiner's position that the amendment of the claims to restrict the limitation, "Q is a cycloalkyl group having from 3 to 10 carbon atoms" to "Q is a cycloalkyl group having from 5 to 10 carbon atoms" constitutes new matter because: "No support is found in the originally filed disclosure for cycloalkyl groups having from 5 to 10 carbon atoms as recited in the instant claims. The only specific compound disclosed contains a cyclohexyl group (i.e., 6 carbon atoms). There are no compounds recited in the original disclosure that would provide support for the limitation of Q being a cycloalkyl group having from 5 to 10 carbon atoms."

As evidence of the inconsistency of the Examiner's position, consider that the original claims, which defined Q as a cycloalkyl group containing 3-10 carbon atoms, were considered by the Examiner to be sufficiently supported to satisfy the Written Description requirement of 35 USC 112. Thus, these claims were never subjected to a "Written Description" rejection on the basis that 35 USC 112 support for this range did not exist in the specification. The Examiner therefore considered the claims to comply with the "written description" requirements of 35 USC 112 with respect to the range of 3-10. Accordingly, if the prior broader claims are supported with respect to the broader range, it is inconsistent to argue that claims that now recite a narrower range are not supported.

It is appellant's position that the Examiner has greatly misinterpreted the law with respect to this issue for the identical reasons stated above in connection with the negative proviso.

See *Ex parte Drewe*, 203 USPQI 127 and *In re Eickmeyer*, 202 USPQ 655. In *Eickmeyer*, the court stated: "the dispositive issue is whether there is support (satisfying

the description requirement of section 112, first paragraph) in appellant's specification and in the parent applications for the claimed temperature limitation of 'at least about 56° C" Further, in *In re Smythe*, 480 F,2d 1376" 178 USPQ 279' (CCPA 1973); the court stated: "[A) statement of appellant's invention [in his specification] which is as broad as appellant's broadest claims" is sufficient to meet this requirement- *In re Robbins*, 57 CCPA 1321, 1325-26, 429 F,2d 452, 456, 166 USPQ 552, 555 (CCPA 1970). . .although appellant may be entitled to claim a range of temperatures below 56°C, he need not claim all that he is entitled to claim and need have support only far what he does claim." (emphasis added).

Accordingly, a reversal of this ground of rejection is respectfully requested.

35 U.S.C. § 103(a)

Regarding the rejection of the claims under 35 U.S.C. § 103(a) as being unpatentable over *Frydman et al.* (U.S. Patent No. 5,889,061; Issued Mar. 30, 1999), Appellant has previously argued that the limitation in the body of the claims that the composition contain "an amount effective" to produce an "anti-diarrheal or gastrointestinal anti-spasmodic" action is a positive structural feature of the claim that cannot simply be ignored by the Examiner when determining the patentability of the claimed invention over Frydman. The Examiner apparently agrees that the limitation in question is a positive structural feature of the claim but insists that it has not been ignored when comparing the claimed invention with Frydman.

Rather, the Examiner now asserts that the amounts of active ingredient in the compositions disclosed in Frydman overlap those ranges of amounts of active agent present in the claimed compositions. Since these ranges overlap, according to the Examiner, the respective compositions are identical notwithstanding the end uses intended therefore. Thus, the Examiner states:

> Appellants argue that the Examiner's rejection of the claims over the cited prior art requires that the limitation in the body of the claims that the composition contain "an amount effective" to produce an "anti-diarrheal or gastrointestinal anti-spasmodic" action be ignored. However, contrary to Appellant's characterization of the rejection, the Examiner does not ignore this claim limitation. Rather, the term "effective amount" as recited in the instant claims is interpreted in light of the specification, which states at page 10 that a "suitable dose of agent will lie in the range of about .0001 mg to about 500 mg per kilogram of mammal body weight being treated". This is a 5 x 10^6 fold range of doses...*Frydman et al.* teach that the pharmaceutical unit dosage chosen is preferably fabricated and administered to provide a concentration of drug at the point of contact with the cancer cell of from 1 μM to 10 μM, preferably from 1 to 100 μM (col. 22, lines 3-7). It would be obvious to one skilled in the art that a composition comprising a compound of *Frydman et al.* to provide a concentration of 1 to 100 μM of compound at the point of contact with a cancer cell when administered to a patient will contain "an effective amount" ranging from about 0.0001 to about 500 mg per kilogram of mammal body weight being treated...Rather, given the broadness of doses defined in the specification, which encompass at least a 5 x 10^6 fold range of doses (i.e., *about* 0.0001 to *about* 500 mg/kg), compositions comprising a compound of Frydman *et al.* for use in the treatment of cancer will necessarily contain an amount of compound falling somewhere within this extremely broad range..." (emphasis Examiner's. in part. And added, in part)

The Examiner merely opines that the ranges necessarily overlap without demonstrating how such is actually the case. Indeed it is virtually impossible to imagine

how the Examiner can reconcile a conclusion that the respective ranges overlap, given that the reference refers to *micromolar* concentrations of the active agent at the site of the cancer cells whereas appellant's specification defines the effective amount in terms of *milligrams* per kilogram of body weight of the individual undergoing treatment.

Until the Examiner shoulders this burden of unequivocally establishing that the ranges overlap, appellant is under no obligation to offer a rebuttal of the Examiner's unsupported allegation.

Having failed to establish a *prima facie* case of obviousness. it is respectfully requested that this ground of rejection be reversed.

The Commissioner is hereby authorized to charge to Deposit Account No. 50-1165 (T2315-907789) any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required in connection with the filing of this paper and has not been separately requested, such extension is hereby requested.

Respectfully submitted,

Date: July 27, 2009

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